

REMARKS

In the Office Action, dated November 26, 2008, the Examiner rejected claims 1, 3, 5-7, 20, 21, 24, and 25 under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over European Patent Document EP 0568045 A1 to Kawata et al. ("*Kawata*"); rejected claim 1 under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,935,141 to Buck et al. ("*Buck*"); and rejected claim 4 under U.S.C. § 103(a) as being unpatentable over *Kawata* in view of *Buck* and U.S. Patent No. 5,707,522 to Maeda et al. ("*Maeda*").

Claims 1, 3-21, and 24-27 are currently pending in this application. Claims 8-19, 26, and 27 were previously withdrawn.

Applicant respectfully traverses the Examiner's rejection of claims 1, 3, 5-7, 20, 21, 24, and 25 under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over *Kawata*. Applicant submits that *Kawata* does not anticipate or render obvious any of the rejected claims.

In order to properly anticipate Applicant's claims under § 102, a single prior art reference must disclose each and every element of the claim at issue, either expressly or under principles of inherency. Further, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." See M.P.E.P. § 2131.

Kawata discloses a "polysulfone hollow fiber membrane . . . [with] an inner dense skin layer composed of a polysulfone and a less amount of a polyvinylpyrrolidone." (Abstract.) *Kawata* also discloses an "outer surface layer." (Abstract.) *Kawata*, however, does not disclose "the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm²" as recited in

independent claim 1. In fact, the Examiner concedes that “EP ‘045 [*Kawata*] differs and does not teach the number of pores present on the outer surface.” (Office Action at 3.) Accordingly, Applicant respectfully asks the Examiner to withdraw the § 102(b) rejection of independent claim 1, because *Kawata* does not disclose each and every element of the rejected claim. Furthermore, the § 102(b) rejection of claims 3, 5-7, 20, 21, 24, and 25 should also be withdrawn, at least due to the dependence of these claims on independent claim 1, and based on their recitations of additional patentable subject matter.

Regarding the § 103 rejection of independent claim 1, several basic factual inquiries must be made in order to determine the obviousness or non-obviousness of claims of a patent application under 35 U.S.C. § 103. These factual inquiries, set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 U.S.P.Q. 459, 467 (1966), require the Examiner to:

- (1) Determine the scope and content of the prior art;
- (2) Ascertain the differences between the prior art and the claims in issue;
- (3) Resolve the level of ordinary skill in the pertinent art; and
- (4) Evaluate evidence of secondary considerations.

The obviousness or non-obviousness of the claimed invention is then evaluated in view of the results of these inquiries. *Graham*, 383 U.S. at 17-18, 148 U.S.P.Q. at 467; see also *KSR Int’l Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385 (U.S. 2007); see also M.P.E.P. § 2141(II). The Examiner states that “EP ‘045 presents a finding that one of ordinary skill in the art could optimize the process conditions to obtain the desired pore

size and number of pores on the surface with a reasonable expectation of success.”

(Office Action at 4.) Applicant respectfully disagrees.

Kawata discloses a dry zone. (Page 7, line 12.) If the dry zone is humidified, “the moisture in air may promote microphase separation or mild coagulation whereby hollow fiber membranes having many micropores of relatively large pore diameters in their outer surface layer can be readily obtained. This effect of the moisture has been recognized even when the dry zone is as short as 0.1 cm. Thus, hollow fiber membranes having a structural feature of the outer surface layer totally different from that of hollow fiber membranes produced by wet processes wherein spun fibers are directly steeped in a coagulating bath, can be obtained.” (Page 7, lines 16-22.) In other words, *Kawata* discloses a method for creating micropores with relatively large pore diameters. *Kawata* also discloses that the method of *Kawata* can be used to create hollow fiber membranes having structural features on the outer surface that are different than those produced by wet processes. However, *Kawata* does not find, teach, disclose, or suggest “optimiz[ing] the process conditions to obtain the desired . . . number of pores” as asserted by the Examiner. (See Office Action at 4, emphasis added.) Therefore, the Examiner has failed to properly determine the scope and content of the prior art as required by *Graham*. Applicant also notes that independent claim 1 recites “pores per mm²” and not just a number of pores. Accordingly, *Kawata* does not teach, disclose or suggest “the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm²” as recited in independent claim 1.

For at least the aforementioned reasons, independent claim 1 is allowable over *Kawata* and the § 103(a) rejection of independent claim 1 should be withdrawn and the claim allowed. Furthermore, dependent claims 3, 5-7, 20, 21, 24, and 25 are allowable at least due to their dependence from independent claim 1 and due to their additional recitations of patentable subject matter.

Applicant also respectfully traverses and requests the withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over *Buck*.

Buck discloses selectively permeable asymmetric membranes. (Abstract.) The membranes are "produced from hydrophobic and hydrophilic polymers . . . [with] a three-layered structure including a first dense thin skin layer which includes uniform pores of a size whereby proteins having a molecular weight of at least that of albumin are substantially rejected therefrom, an intermediate second layer in the form of a sponge and having a higher diffusive permeability than the first layer, and a third layer with a finger-like structure which provides mechanical stability. These membranes are preferably formed in the shape of hollow fibers, with the first layer as the inner layer thereof." (Abstract.)

Buck does not teach, suggest, or disclose "a fourth outer layer in the form of a sponge layer having an outer surface having pores with sizes in the range of 0.5-3 μm , the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm^2 " as recited in independent claim 1. The Examiner concedes that *Buck* "does not teach a fourth layer in the form of a sponge" (Office Action at 5.) The Examiner, however, contends that a "side-by-side comparison of the

photomicrographs of Buck '141 and the current application [indicate] that the prior art to Buck has the same structure as the current application." (Office Action at 5-6.)

Applicant strongly disagrees.

As stated in M.P.E.P. 2112(IV), "[t]o establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" M.P.E.P. 2112(IV), (emphasis added). However, "[w]here the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established." M.P.E.P. 2112.01(l)

The Examiner has not established inherency at least because the express disclosure of *Buck* teaches "a three-layered structure." (Abstract.) The express disclosure of *Buck* therefore rebuts any presumptions presented by the Examiner. Furthermore, the Examiner has provided no analysis as to why the figure from *Buck* and the figure from the instant Application are similar or why the alleged similarities would provide for "a fourth outer layer in the form of a sponge layer having an outer surface having pores with sizes in the range of 0.5-3 μm , the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm^2 " as recited in independent claim 1. Applicant submits that when "relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic

necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). The Examiner has failed to meet this burden.

Accordingly, for at least the aforementioned reasons, *Buck* does not disclose each and every element of independent claim 1, and thus, the § 102(b) rejection of independent claim 1 should be withdrawn. Moreover, as discussed above, *Buck* also fails to suggest each and every element of independent claim 1. Therefore, the § 103 rejection of independent claim 1 should also be withdrawn and the claim should be allowed.

Applicant respectfully traverses the Examiner's rejection of claim 4 under 35 U.S.C. § 103(a) as being unpatentable over *Kawata* in view of *Buck* and *Maeda*. Applicant respectfully disagrees.

Maeda discloses "a permselective membrane of the polyacrylonitrile copolymer of the kind as described above which is an asymmetric membrane having, as the outermost layer, a dense layer (skin layer) having a thickness of 0.05 to 5 μm and substantially free from pores having a pore size of at least 0.5 μm ." (Col. 3, lines 19-24.)

Maeda, however, does not disclose "the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm^2 " as recited in independent claim 1. Accordingly, *Maeda* does not remedy the deficiencies described above. For at least this reason, the Examiner should withdraw the § 103 rejection of claim 4 and allow the claim.

CONCLUSION

In view of the foregoing remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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